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May 21, 2024

Honorable Michael A. Shipp, U.S.D.J.
United States District Court
Clarkson S. Fisher Building & US Courthouse
402 East State Street
Trenton, NJ 08608

Honorable Rukhsanah L. Singh, U.S.M.J.
United States District Court
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street
Trenton, NJ 08608

**Re: Johnson & Johnson Talcum Power Products, Marketing, Sales Practices and
Products liability Litigation
Case No.: 3:16-md-02738-MAS-RLS**

Dear Judge Shipp and Judge Singh:

I write on behalf of the Johnson & Johnson defendants in response to plaintiffs' letter of May 17 (doc. 32197) regarding Katie O'Brien, et al., *Intimate Care Products & Incidence of Hormone-Related Cancers: A Quantitative Bias Analysis* ("O'Brien (2024)"), a new article published in the Journal of Clinical Oncology.

In brief, this new article does not support the conclusion that talcum powder exposure can cause ovarian cancer, as the authors themselves acknowledged. See O'Brien (2024) at 13 ("These results do not establish causality and do not implicate any specific cancer-inducing agent."). Rather, the *actual data* generated by the study demonstrates that there is "*inverse or weakly positive associations* between [talc] and all cancers of interest." *Id.* at 12. The authors derived a positive association between genital talc exposure and ovarian cancer only by (i) assuming respondents who initially reported that they "never" used talc actually did, solely because they did not respond to subsequent use inquiries; and then (ii) assigning or imputing levels of "use" to those respondents that did not actually exist in the data. Without those assumptions, O'Brien (2024) reports no association.

O'Brien (2024) grows out of a *prospective* cohort study, the Sister Study, in which talc exposure was ascertained at enrollment. The results of that study have previously been published and did not show a positive association between talc and ovarian cancer. Thereafter, O'Brien and her colleagues sought to collect additional data through a *retrospective* follow-up questionnaire sent to the same women. However, that follow-up questionnaire, together with the responses and work that followed, resulted in two critical problems.

First, inherent in the use of any retrospective questionnaire is the possibility of recall bias. Here, among those who did answer the follow-up questionnaire, the results suggested substantial recall bias. This is not surprising, since the follow-up questionnaire was conducted between 2017 and 2019, at the height of publicity about talc litigation, a fact noted in other published studies. The authors attempted to "correct" for this substantial recall bias by adjusting what they termed "contradictory data." That means, for some respondents who reported exposure in the follow-up

Honorable Michael A. Shipp, U.S.D.J. Honorable Rukhsanah L. Singh, U.S.M.J

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questionnaire that was inconsistent with their responses to exposure questions in the enrollment questionnaire, the authors “corrected” (changed) their responses. But there is *no accepted methodology* for making such “corrections.”

Second, and even more significantly in terms of outcome, a substantial portion of the original survey population did not complete the most recent follow-up questionnaire, and ovarian cancer patients were overrepresented in that missing group. The authors also attempted to address the “missing” use data by imputing, *i.e.*, predicting levels of talc use. They modeled two scenarios based on imputed data that show a statistically significant association. In one hypothetical, the authors assumed that every missing respondent would have used talc. In this scenario, the authors calculated a hazard ratio of 3.34, which they admit is an overestimate. In another hypothetical, the authors assumed that all missing respondents who reported talc use at enrollment would have reported use in the follow-up questionnaire. Further, for missing respondents who initially reported no exposure, the authors attempted to predict results based on factors including wealth, education, marital status, and diagnosis with gynecological cancers, though their exact methodology is left opaque. This exercise produced a hazard ratio of 1.82 with a confidence interval of 1.36-2.43 – much higher than any previous study (including nearly all the case-control studies relied on by plaintiffs in the litigation and those co-authored by their own experts). *See id.*

Critically, the authors make no effort to suggest or explain the methodology that led to or would support their imputation criteria, and the only certainty from the study is that the predictive factors are associated with an increased ovarian cancer risk, potentially raising concerns about confounding. Yet the authors’ claim of a “positive association between genital talc use and ovarian cancer” that was “higher for frequent . . . and long-term . . . users,” *id.* at 13 (quoted in Pls.’ Ltr.), is based *entirely* on these imputed “results.”

In sum, O’Brien (2024) is, at base, a retrospective study whose results are not derived from the actual data. Instead, it is premised entirely on “corrections” that lack a generally accepted methodology, and a series of assumptions leading to imputations that drive its results. The study does not, and due to design cannot, change the well-established scientific landscape.

Thank you for your continued consideration of these matters.

Respectfully submitted,



Susan M. Sharko

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All counsel via ECF